

We claim:

- A method for treating a human patient afflicted with cancer, comprising administering therapeutically effective amounts of temozolomide and irinotecan to such a patient for a time period sufficient to effect at least a partial tumor response.
- The method of claim 1, wherein the irinotecan is in the form of a hydrochloride salt.
 - The method of claim 1, wherein the temozolomide and irinotecan are administered over repeated 21 day cycles, where said 21 day cycles are divided into three 1 week periods.
 - The method of claim 3, wherein the total amount of irinotecan administered over the 21 day period ranges from 3 to 400 mg/m² of the patient's body surface.

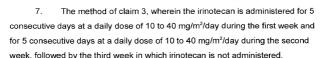
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5. The method of claim 3, wherein the amount of temozolomide administered over the 21 day period ranges from 50-200 mg/m²/day of the patient's surface and wherein said temozolomide is administered for 5-14 days over the 21 day period.

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6. The method of claim 3, wherein the amount of temozolomide administered over the 21 day period ranges from 50-200 mg/m²/day of the patient's surface and wherein said temozolomide is administered for 5-14 days over the 21 day period and the irinotecan is in the form of a hydrochloride salt.



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8. The method of claim 7, wherein the temozolomide is administered for 5 consecutive days at a daily dose of 100 to 200 mg/m²/day during the first week, followed by the second and third week in which temozolomide is not administered

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The method of claim 7, wherein the temozolomide is administered for 5 to 7 consecutive days at a daily dose of 100 to 200 mg/m²/day during the first and third weeks of the 21 day cycle.

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10 The method of claim 7, wherein the temozolomide is administered for 5 to 7 consecutive days at a daily dose of 100 to 200 mg/m²/day during the first and second weeks of the 21 day cycle.

The method of claim 9, wherein the irinotecan is in the form of a

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hydrochloride salt.

12 The method of claim 10, wherein the irinotecan is in the form of a hydrochloride salt.

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13 The method of claim 3, wherein the irinotecan is administered on a single day of the 21 day cycle in an amount of from 250 to 650 mg/m².

a week during the 21 day cycle at a dose of from 100 to 125 mg/m².

The method of claim 3, wherein the irinotecan is administered once

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The method of claim 3 wherein the temozolomide and irinotecan 15. are both administered on the first day of the 21 day treatment cycle.

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- The method of claim 15, wherein the irinotecan is in the form of a hydrochloride salt.
- 5 17. The method of claim 1, wherein the temozolomide is administered prior to the administration of the irinotecan.
 - 18. The method of claim 3, wherein the temozolomide and irinotecan are administered in three 21 day cycles, each cycle having a dosing period wherein the temozolomide is administered for the first five days of the 21 day cycle at a daily dose of 50 to 200 mg/m²/day, the irinotecan is administered with the temozolomide for the first 5 days of the 21 day cycle and for an additional 5 day period during the second week of the 21 day cycle at a daily dose of 10 to 40 mg/m²/day, followed by the third week in which temozolomide and irinotecan is not administered.
 - The method of claim 17, wherein the temozolomide is administered orally and the irinotecan is administered intravenously.
 - The method of claim 1, wherein the temozolomide and irinotecan are administered over repeated 28 day cycles.
 - 21. The method of claim 20, wherein the total amount of irinotecan administered over the 28 day period ranges from 3 to 400 mg/m² of the patient's body surface.
 - 22. The method of claim 20, wherein the amount of temozolomide administered over the 28 day period ranges from 50-200 mg/m²/day of the patient's surface and wherein said temozolomide is administered for 5-14 days over the 28 day period.

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- 23. The method of claim 20, wherein the amount of temozolomide administered over the 28 day period ranges from 50-200 mg/m²/day of the patient's surface and wherein said temozolomide is administered for 5-14 days over the 28 day period and the irinotecan is in the form of a hydrochloride salt.
- 24. The method of claim 20, wherein temozolomide and irinotecan are administered over a 28 day cycle, wherein the temozolomide is administered on days 1-14 of said cycle at a daily dose of 75 to 150 mg/m²/day and wherein the irinotecan is administered on day 8 of said cycle at a daily dose of 100 to 350 mg/m²/day.
- 25. The method of claim 24, wherein the temozolomide is administered orally and the irinotecan is administered intravenously
 - 26. A medical kit for treating a cancer patient is provided, comprising:
 - (a) a supply of temozolomide:
 - (b) a supply of irinotecan; and
 - printed instructions for administering temozolomide and irinotecan to a cancer patient.